

Concept Clearance – New Early Stage Investigator HIV/AIDS Research Using Nonhuman Primate (NHP) Models Program (R21)

The purpose of this new program is to address (1) the pressing problem of a shortage of new researchers applying nonhuman primate (NHP) models to preclinical HIV/AIDS topics and (2) the challenges early stage investigators have with entering the NIH funding system with their first research award, particularly when using expensive NHP models.

Individually, the [NIH Strategic Plan for HIV and HIV-Related Research](#) for FY2019/2020 identified a deficit of new HIV researchers, and ORIP's [Report of the Expert Panel Forum on Challenges in Assessing Nonhuman Primate Needs and Resources for Biomedical Research](#) emphasized a need to increase the supply of skilled NHP researchers in the United States. Together, these documents reveal an inadequate supply of researchers using NHPs to address preclinical topics in HIV/AIDS.

Similarly, the NIH and Congress have recognized the overall challenges new researchers have in acquiring funding and establishing independent careers. As an example, the age of PIs on research project grants (RPGs) has steadily increased over the decades, [reaching an average of 53 years in 2015](#). In 2001 the percentage of PIs with an RPG aged 66 or greater exceeded the percentage of PIs less than 36 years old for the first time, and the gap has continued to increase. In 2015, the percentage of PIs of RPGs less than 36 years old was below 4%. Partially in recognition of these facts, the 21st Century Cures Act, enacted in 2016, included language that requires the NIH Director to “Develop, modify, or prioritize policies, as needed, within the National Institutes of Health to promote opportunities for new researchers and earlier research independence, such as policies to increase opportunities for new researchers to receive funding, enhance training and mentorship programs for researchers, and enhance workforce diversity.”

There are many potential contributing factors to the diminishing success rates for young investigators. Among the more likely explanations is the increasing need for young researchers to be reliant on research funding support from a senior lab head and their resulting inability to establish a unique research program and preliminary data for an independent research proposal. To address this problem, some NIH institutes have established expanded R21 programs directed at new researchers that exceed the standard \$275,000 budget cap for that mechanism.

For example, the NIDCD has an [Early Career Researcher R21](#) established in FY16 that awards \$100,000 per year for three years to applicants who are no more than seven years beyond their terminal degree. The rationale for focusing on the R21 mechanism is that receipt of the R21 award appears to improve success rates in competing for a subsequent R01 award. In FY15 across the NIH, 12% of new investigators and early stage investigators who applied for an R01 who did not have a prior R21 were successful, while 26% of new investigators and early stage investigators who had previously received an R21 were successful. Based on this NIH-wide data, NIDCD anticipates an increased proportion of its new investigators and early stage investigators obtaining subsequent R01 funding.

Also seeing the R21 as a beneficial aid to successfully competing for larger RPGs, NIBIB established in FY16 the [Trailblazer Award for New and Early Stage Investigators R21](#), which awards up to \$400,000 over three years. In FY15, the year before establishing the new R21 program, 18% of NIBIB R21 awards went to new investigators and early stage investigators. By FY19, 63% of NIBIB R21s were awarded to new investigators and early stage investigators.

In order to address the shortage of young researchers with the skills to use NHPs in preclinical HIV/AIDS research and to assist these researchers in achieving independent research careers, ORIP proposes to establish the Early Stage Investigator HIV/AIDS Research Using Nonhuman Primate (NHP) Models Program (R21), developed in collaboration with the Office of AIDS Research. A larger than standard budget for the R21 awards was chosen due to the high costs associated with NHP research and the desire to provide recipients with the funds to develop independent research projects. Key elements of the program are:

- \$200,000 per year for two years
- At least two years prior postdoctoral experience
- Applicants no more than 10 years beyond their terminal professional degree
- Documented affiliation with a primate center with staff skilled in NHP research
- Research focused on preclinical HIV/AIDS topics

ORIP anticipates that the benefits of the expanded R21 to the successful applicants will include:

- Increased fiscal independence allowing recipients to pursue research directions independent of the support of their mentor;
- Ability to demonstrate additional success through competition in the peer review process; and
- Generation of additional data and publications in support of future R01 applications.

At the end of the fifth year of R21 competitions, ORIP will begin to evaluate the impact of the awards on the career trajectories of those who received them. These data should provide ORIP with a basis to decide whether the R21 program warrants longer term investments.

Considering the need for transition support to the first R01 grant for early stage investigators using NHP models for preclinical HIV/AIDS research, ORIP requests concept clearance from the Council of Councils to support the Early Stage Investigator HIV/AIDS Research Using Nonhuman Primate (NHP) Models Program (R21).